

**REMARKS**

Review and reconsideration on the merits are requested.

**Interview Summary**

No agreement was reached.

Applicants argued that the "consisting essentially of" language excluded Bezwada (later identified). The Examiner took the position that "hydrophilic polymer" was broad enough to include the Bezwada polyoxaester.

The Examiner also took the position that the language added at the end of claim 1 was unclear since the Examiner felt the language made claim 1 indefinite as to whether it was directed to a substrate, a combination with an adhesive sheet or some other subject matter.

Applicants also argued claim 17, but the Examiner's position was simply that Webster taught an adhesive layer as claimed and was properly combined with Bezwada.

With respect to the Bezwada bioabsorbable material, Applicants argued that this was quite distinct from the present invention, e.g., Bezwada teaching a suture and the like which would be absorbed. However, the Examiner took the position that "bioabsorbable" fell within "absorbable".

The Examiner's position was that Declaration evidence should be submitted.

Applicants now turn to the Action.

Regarding the rejection under 35 U.S.C. § 112, second paragraph, Applicants combine claims 1 and 17, canceling claims 1-9. It is believed this meets the Examiner's request for clarification.

In addition to including the limits of claim 1 into claim 17, Applicants include the limits of claim 5 into claim 17. If the Examiner would find the combination of claims 1 and 17 allowable, Applicants offer to withdraw the inclusion of claim 5, and change all of claims 2-9 to depend from claim 17. Applicants would also offer to file a claim directed to the "crosslinking" aspect of the invention.

Withdrawal of the rejection is requested.

#### **The Prior Art**

U.S. 5,607,687 Bezwada et al (Bezwada); U.S. 4,541,426 Webster.

With the combination of claims 1 and 17 (and claim 5), the only rejection remaining would be an obviousness rejection over Bezwada in view of Webster.

Applicants would traverse such rejection for the reasons set forth below.

#### **The Invention**

The present invention relates to an adhesive sheet which consists of a substrate film and an adhesive layer and a substrate film which is uniquely adapted to be used with such an adhesive sheet.

A major aspect of the present invention resides in the composition of the substrate film recited in claim 17 which is characterized by comprising an elastomer resin and a hydrophilic polymer having a higher modulus strength than the elastomer resin.

#### **Bezwada**

Bezwada discloses polymer blends comprising a polyoxaester as a main component. The Bezwada blend has a specific composition and shows bioabsorbable properties. Bezwada

discloses materials which may be used for surgical operations such as a suture and medical materials. Thus, even though Bezwada and the present invention involve the use of a polymer, the technical field and objects in Bezwada are quite dissimilar from those of the present invention.

As the Examiner will appreciate, the adhesive sheet of the present invention is not bioabsorbable. A bioabsorbable adhesive sheet would, in a short period of time, turn out to be useless for purposes of the present invention.

Bezwada is best directed to polymer blends containing bioabsorbable polyoxaesters. The present invention is directed to an adhesive tape which firmly attaches to a substrate, typically the skin, and maintains such attachment and maintains flexibility even when sweat or moisture is absorbed. The tape of the present invention cannot be bioabsorbable, and is used as an adhesive which will not dissolve. If the adhesive were to dissolve, the function of the tape of the present invention would be destroyed. The tape of the present invention exhibits the above effects by adopting a specific mixing ratio of an elastomer resin and a hydrophilic polymer.

Although Bezwada discloses various uses in many different types of material and devices, particularly absorbable items, Bezwada in no fashion discloses or suggests adhesive use as in the present invention.

Referring to claim 17, there is no disclosure in Bezwada of "having a tensile modulus of elasticity higher than that of the elastomer resin", nor is there any disclosure of the tensile modulus of elasticity in a saturated water absorption state, etc.

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For these limits, the Examiner must be relying upon an inherency position. However, the Examiner's inherency position is conclusionary. Such a conclusionary approach has been criticized by the Board.

The Examiner's attention is directed to the *Schricker* and *Skinner* decisions now discussed.

"Inherency and obviousness are somewhat like oil and water - they do not mix well... However, when an Examiner relies on inherency, it is incumbent on the Examiner to point to the "page and line" of the prior art which justifies an inherency theory. *Compare In re Rijckaert*, 9 F.3d 1531, 1533, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (when the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the prior art) (citing *In re Yates*, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981),"

*Ex parte Schricker*, 56 USPQ2d 1723 (Bd. Pat. App. & Int. 2000), unpublished.

"It is by now well settled that the burden of establishing a *prima facie* case of anticipation resides with the Patent and Trademark Office. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984) quoting *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173, 177 (CCPA 1967). It is the Examiner's position that the mold of Mizutani may inherently have the characteristics of the claimed mold. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Olerich*, 666 F.2d 578, 581, 212 USPQ 323 (CCPA 1981). We are mindful that there is a line of cases represented by *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971) which indicates that where an Examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, the Examiner possesses the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. Nevertheless, before an applicant can be put to this burdensome task, the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that the functional limitation is an inherent characteristic of the prior art. In the case before us, no such evidence or reasoning has been set."

*Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Int. 1986).

Specifically, the Examiner has advanced no basis why the limitation that the hydrophilic polymer have a tensile modulus of elasticity higher than that of the elastomer resin is shown in Bezwada nor has the Examiner advanced any scientific reason supporting the inherency of the tensile modulus of elasticity in a saturated water absorption state. Applicants respectfully submit that the Examiner has failed to carry his burden of proof in this regard, and for that reason alone, the rejection should be withdrawn.

With respect to the Examiner's position on inherency, Applicants might agree with the Examiner that if a claimed product and a prior art product are shown to be identical or substantially identical in structure or composition, etc., a *prima face* case of anticipation or obviousness has been established. However, in the present instance Applicants respectfully submit that the products claimed herein and the Bezwada products are not identical or substantially identical in structure or composition. The Bezwada products are bioabsorbable and this apparently is due to the critical presence of the aliphatic polyoxaesters of Bezwada. Applicants respectfully submit that the "consisting essentially of" of the present claims would exclude substantial proportions of the aliphatic polyoxaesters as in Bezwada which are needed to make the Bezwada product bioabsorbable.

With respect to claim 5 (now in claim 17), specifically the Examiner's position regarding a suitable weight ratio between the hydrophilic polymer and the elastomer resin, Applicants respectfully submit the Examiner to be in error at this point. If the products of the present invention were bioabsorbable, contrary to the essence of the present invention, then there might be some validity to the Examiner's position. However, the products of the present invention **are**

**not bioabsorbable**, and thus quite clearly the products claimed and the Bezwada products cannot be identical or substantially identical in structure or composition, etc. Certainly, there would be no reason for one to select a weight ratio to achieve the results of the present invention as set forth in claim 17 from the teaching of Bezwada.

For all of the above reasons, withdrawal of any rejection based in whole or in part on Bezwada is requested. Webster is later discussed.

Applicants would now like to address certain specific points in the Action.

Turning to page 4 of the Action, in part of the last sentence, the Examiner states as follows:

“[I]t is the Examiner's position that, in the absence of evidence to the contrary, the relative strength of the tensile moduli of the absorbable film in water saturated state and dry state is either anticipated in Bezwada, or obviously provided once the same polymers are selected.”

Applicants respectfully submit that the problem with the above reasoning is the fact that it is predicated upon "provided once the same polymers are selected". There is nothing in Bezwada that suggests the use of a hydrophilic polymer having a tensile modulus of elasticity higher than that of the elastomer resin. There is nothing in Bezwada suggesting the tensile modulus of elasticity in a saturated water absorption state, etc. There is no scientific reasoning provided to support the conclusion that these limits of claim 17 are met.

With respect to the Examiner's statements at the bottom of page 4 of the Action regarding "consisting essentially of", Applicants respectfully submit that given the limits of claim 17 calling for an adhesive sheet comprising an adhesive layer formed on at least one surface of the

substrate film, that the "consisting essentially of" language excludes a material as in Bezwada which would, simply stated, dissolve.

Turning now to the first full paragraph on page 5 of the Action, the Examiner states, in part:

“[T]here is not any functional language present in the claims to limit such to any particular utility such that the products of Bezwada would be unable of performing.”

As Applicants have earlier pointed out, Bezwada in no fashion suggests any adhesive use. Accordingly, Applicants respectfully submit that there is functional language defining a particular utility that the products of Bezwada would be in capable of performing.

With respect to page 5, second full paragraph of the Action, the term "not bioabsorbable" does not occur in the present specification. Applicants would be willing to insert into the claims any reasonable language which would reflect "not bioabsorbable" which would find support in the specification. If the Examiner has any suggestions, they would be appreciated.

Turning to the paragraph bridging pages 5/6 of the Action, in view of the combination of claims 1/17, quite clearly patentable weight should now be attached to the limit which the Examiner has criticized.

Turning to Webster, at page 6 of the Action, the Examiner states in part as follows:

“[T]he Examiner repeats that Webster's invention is directed to a dressing suitable for application to lesions of the skin (i.e., would dressing), which is inherently a bioabsorbable material...”

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The Examiner's attention is directed again to the *Schricker* and *Skinner* decisions. There must be **some basis** on the record for the Examiner to conclude inherency. Such is lacking on this record.

Applicants now address Webster.

Applicants again submit that what is lacking is motivation to combine Bezwada and Webster.

Webster discloses a dressing comprising a conformable aperture film. This has no relationship to an adhesive sheet in accordance with the present invention nor, in fact, is there any relationship between Webster and the bioabsorbable material of Bezwada. The Webster product is a laminated dressing which has a reduced tendency to adhere to skin lesions. In distinction, the tensile modulus of elasticity of the present invention is specified as being sufficient and comfortable for attachment over the skin, and this is now emphasized in claim 17.

Applicants respectfully submit that claim 17 is patentable for the reasons advanced.

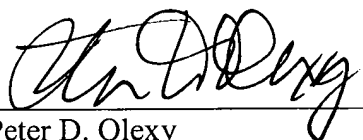
In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.



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Respectfully submitted,



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